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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,863	03/31/2004	Edward Vaquero	P03166	5586

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EXAMINER	
LANG, AMY T	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,863	VAQUERO, EDWARD	
	Examiner	Art Unit	
	Amy T. Lang	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/19/05, 7/6/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. **Claims 1, 6, and 8-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett (US 5,935,096).

With regard to **claims 1, 6, and 8-11**, Barrett discloses a device comprising a lumen (13) extending within, wherein the lumen terminates at the distal tip (18) of the device (column 4, lines 24-32; Figure 2B). The increase in diameter of the lumen, as shown in Figures 7A through 7D, is either gradual (Figure 7B) or stepped (Figures 7A, 7C, and 7D). Furthermore, the outer diameter of the device body is substantially constant (Figures 7A through 7D).

The introductory statement of intended use ("for injecting a foldable IOL into eye") has been carefully considered but deemed not to impose any structural limitations on the claims of patentably distinguishable over Barrett's device, which is capable of being used as claimed if one desires to do so.

2. **Claim 14** is rejected under 35 U.S.C. 102(b) as being anticipated by Green (US 6,471,708 B2).

Green discloses a device for injecting an IOL into an eye comprising a lumen and plunger (column 2, lines 54-57; column 3, lines 13-15). The lumen (18) extends throughout the length of tubular member (22) and terminates at distal tip (28) (Figure 1). The IOL is directed into the eye through distal tip (28) (column 6, lines 63-67). The

plunger (32) is further disclosed as engaging and pushing the IOL through the distal tip and into the eye (column 4, lines 19-31). This is accomplished wherein the plunger is advanced into the lumen (column 4, lines 28-31). As shown in Figure 1, the diameter of the plunger tip (36) is smaller than the diameter of the lumen to produce a close, sliding fit.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

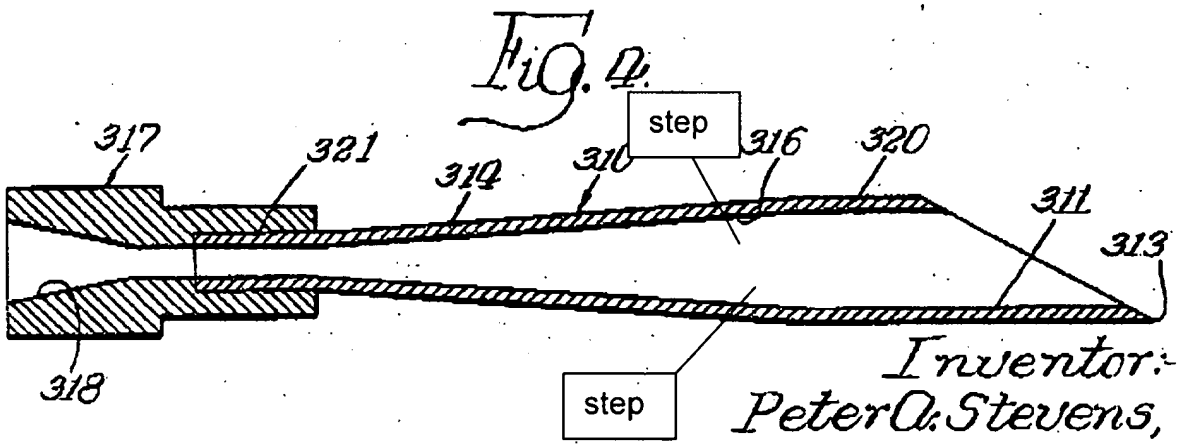
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1, 7-9, 12, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (US 3,386,438).

With regard to **claims 1, 7-9, 12, and 13**, Stevens discloses a cannula comprising an inner lumen terminating at an open tip (column 2, lines 28-39). Stevens teaches that a cannula is associated with other devices, including a syringe, so that it

would have been obvious to for the cannula of Stevens to be incorporated with a syringe (column 1, lines 23-25). The cannula, as shown in Figure 1, discloses the lumen as gradually increasing in diameter toward the distal tip (11). The diameter of the outer body increases along with the increase in diameter of the lumen (Figures 1 through 4). Additionally, Figure 4 discloses a step in the lumen increase in diameter as indicated below.

The introductory statement of intended use ("for injecting a foldable IOL into eye") has been carefully considered but deemed not to impose any structural limitations on the claims of patentably distinguishable over Stevens' device, which is capable of being used as claimed if one desires to do so.



6. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (US 3,386,438) in view of Barrett (US 5,935,096).

Stevens discloses a device comprised of an inner lumen increasing in diameter toward distal tip. However, if applicant were to argue that Stevens does not explicitly disclose wherein the increase in diameter is stepped, Barrett also discloses a device

comprising an inner lumen that increases in diameter toward distal tip. As shown in Figures 7A, 7C, and 7D, the increase in diameter is disclosed as stepped. Since this embodiment is known in the art and the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result, this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the lumen of Stevens to be distally expanding in a stepped configuration.

7. **Claims 1, 4, 5, 14, 16, 17, 20, and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (US 3,386,438) in view of Callahan (US 2005/0033308 A1).

With regard to **claims 1, 4, 5, 14, 16, 17, 20, and 21**, Stevens discloses a cannula comprising an inner lumen increasing in diameter toward a distal tip. Stevens teaches that a cannula is associated with other devices, including a syringe, so that it would have been obvious to for the cannula of Stevens to be incorporated with a syringe (column 1, lines 23-25).

Stevens does not specifically disclose the syringe as comprised of a plunger. Callahan discloses a device for inserting an IOL into a patient's eye ([0016]). The device comprises a syringe (101) having a plunger disposed within the lumen of the syringe (Figure 13). Additionally the plunger has a longitudinal shaft and diameter

smaller than the diameter of the lumen as shown in Figure 13. Since Callahan discloses the use of a plunger in a syringe for inserting a material into an eye, it would have been obvious to one of ordinary skill in the art at the time of the invention for the syringe of Stevens to comprise a plunger.

8. Claims **1-5, 14, 15, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (US 6,471,708 B2) in view of Stevens (US 3,386,438).

With regard to **claims 1, 4, and 5**, Green discloses a device for injecting an IOL into an eye comprising a lumen and plunger (column 2, lines 54-57; column 3, lines 13-15). The lumen (18) extends throughout the length of tubular member (22) and terminates at distal tip (28) (Figure 1). The IOL is directed into the eye through distal tip (28) (column 6, lines 63-67). The plunger (32) is further disclosed as engaging and pushing the IOL through the distal tip and into the eye (column 4, lines 19-31). This is accomplished wherein the plunger is advanced into the lumen (column 4, lines 28-31). As shown in Figure 1, the diameter of the plunger tip (36) is smaller than the diameter of the lumen to produce a close, sliding fit.

The distal tip of Green comprises a cannula (28) (column 6, lines 63-67). However, Green does not specifically disclose the lumen as increasing in diameter and terminating at the distal opening of the cannula. Stevens discloses a cannula comprising an inner lumen terminating at an open tip (column 2, lines 28-39). The cannula, as shown in Figure 1, discloses the lumen as gradually increasing in diameter toward the distal tip (11). The diameter of the outer body increases along with the

increase in diameter of the lumen (Figures 1 through 4). Additionally, Figure 4 discloses a step in the lumen increase in diameter. The increase in diameter of the lumen disclosed by Stevens minimizes friction between the device and tissue that reduces associated pain. Therefore, since this configuration is disclosed as advantageously reducing pain, it would have been obvious to one of ordinary skill at the time of the invention for the device of Green to incorporate a distally expanding lumen.

With regard to **claims 2 and 15**, the device disclosed by Green comprises a loading bay (void 66) in which an IOL is inserted for proper implantation within the eye (column 5, lines 14-25).

With regard to claims **3 and 19**, the device disclosed by Green comprises a compressor drawer (compressor 40) with a leading edge (interior wall 62) to engage and compress the IOL (column 4, lines 56-60; Figures 6A through 6C). As shown in Figure 1, the compressor is adjacent the loading bay (66).

9. **Claims 18 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (US 6,471,708 B2) in view of Stevens (US 3,386,438) and Barrett (US 5,935,096).

With regard to **claim 18**, the combination of Green and Stevens discloses a device for inserting an IOL into an eye, wherein the device comprises a lumen increasing in diameter toward distal tip. However, this combination does not specifically disclose the outer diameter as substantially constant. Barrett also discloses a lumen increasing in diameter toward the distal tip. As shown in Figure 7B, the outer diameter

of the device is substantially constant along where the lumen diameter increases. Therefore, since this embodiment is known in the art and the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result, this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the lumen of Green to be distally expanding while the outer diameter of the device remains substantially constant.

With regard to **claim 21**, Stevens discloses a device comprised of an inner lumen increasing in diameter toward distal tip. However, if applicant were to argue that Stevens does not explicitly disclose wherein the increase in diameter is stepped, Barrett also discloses a device comprising an inner lumen that increases in diameter toward distal tip. As shown in Figures 7A, 7C, and 7D, the increase in diameter is disclosed as stepped. Since this embodiment is known in the art and the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result, this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the lumen of Stevens to be distally expanding in a stepped configuration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/21/06
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ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
12/22/06.